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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/098,555	05/05/1995	LINDA G. CIMA	MH16210	7284

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EXAMINER

RUSSEL, JEFFREY E.

ART UNIT PAPER NUMBER

1654

DATE MAILED: 10/29/2002

38

Please find below and or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/398,555

Applicant(s)

CIMA ET AL

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other

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1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 14-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,906,828. Although the conflicting claims are not identical, they are not patentably distinct from each other. It is the examiner's position that a one-way test is appropriate for obviousness-type double patenting. The instant generic claims are anticipated by the narrower claims of the '828 patent and one-way obviousness (i.e. of the instant claims over the claims of the '828 patent) is therefore satisfied.

3. Claim 32 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 20 of U.S. Patent No. 6,045,818. Although the conflicting claims are not identical, they are not patentably distinct from each other. It is the examiner's position that a one-way test is appropriate for obviousness-type double patenting. The instant generic claims are anticipated by the narrower claims of the '818 patent and one-way obviousness (i.e. of the instant claims over the claims of the '818 patent) is therefore satisfied.

4. The three prior art rejections which were vacated in the decision by the Board of Patent Appeals and Interferences mailed July 27, 2001 (see page 9 of the decision) are hereby reiterated. In particular:

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(1) Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herweck et al in view of Merrill (U.S. Patent No. 5,171,264) for the same reasons set forth in the Examiner's Answer mailed January 12, 1998.

(2) Claim 17 is rejected under 35 U.S.C. 103(a) as being obvious over Herweck et al in view of Merrill (U.S. Patent No. 5,171,264) and further in view of Mikos for the same reasons set forth in the Examiner's Answer mailed January 12, 1998.

(3) Claims 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application '616 for the same reasons set forth in the Examiner's Answer mailed January 12, 1998.

5. Applicant's arguments filed August 21, 2002 have been fully considered but they are not persuasive.

The rejection of claims 14-17 under 35 U.S.C. 102(b) over the WO Patent Application '616 is maintained. Applicants point out that the only examples of the WO Patent Application '616 demonstrate tethering of collagen, hyaluronic acid, and fibronectin. However, this argument supports the examiner's conclusion of anticipation, because collagen is disclosed by Applicants to be an extracellular matrix molecule, which is a preferred growth effector molecule for the purposes of Applicants' invention (see page 10, lines 22-23, and page 11, lines 11-12, of Applicants' specification). Accordingly, Applicants' claims clearly embrace at least one of the biomolecules exemplified by the WO Patent Application '616. In any event, the disclosure of a reference is not limited to the reference's examples and most preferred embodiments, and the WO Patent Application '616's disclosure of ECGF, FGF, and PDGF (see page 7, lines 14-27) further supports the examiner's position of anticipation.

Applicants point out that the WO Patent Application '616 does not report enhanced growth rates. However, patentability can not be based merely upon the employment of descriptive language not chosen by the prior art. In re Skoner, 186 USPQ 80, 82 (CCPA 1975). The mere recitation of a newly discovered function or property inherently possessed by things in the art, does not cause a claim drawn to these things to distinguish over the prior art. In re Swinehart, 169 USPQ 226 (CCPA 1971). Sufficient evidence of similarity is present between the compositions of the WO Patent Application '616 and Applicants' claimed compositions to permit a conclusion that the property of enhanced growth of cells is inherent in the prior art. This conclusion is not rebutted merely by arguing that the prior art does not recite the property; rather, the conclusion must be rebutted by arguments or evidence that the prior art composition does not actually possess the property. See also pages 10-15 of the Decision on Appeal mailed July 27, 2001, upholding a prima facie case of anticipation based upon the same reference.

Applicants argue that the WO Patent Application '616 does not teach or suggest how to avoid rounding up and non-adherent cells, does not teach or suggest Applicants' proper amounts of tethered growth effector molecules, does not teach or suggest tethers that can bind more than one biomolecule, does not teach or suggest binding more than one type of growth effector molecule to the same substrate, does not teach or suggest multi-functional flexible tethers, etc. However, none of these disclosed aspects of Applicants' invention are actually claimed by Applicants, and patentability must be based upon claimed, not unclaimed, differences over the prior art.

The rejection of claims 14-16 under 35 U.S.C. 103(a) over Herweck et al in view of Merrill (U.S. Patent No. 5,171,264) is maintained. Applicants argue that there is no suggestion

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in either reference to incorporate the teaching of the other reference. However, this argument does not set forth the correct test of obviousness under 35 U.S.C. 103. Obviousness must be determined on the basis of the prior art when considered as a whole, not on the basis of any single reference. Further, the teaching, suggestion, or motivation to combine references under 35 U.S.C. 103 can be implicit rather than explicit. See MPEP 2143.01. Merrill teaches that the bioapplications contemplated for its immobilized polyethylene oxide star molecules include biomedical applications in which blood contact is involved, e.g., intravenous catheters and implantable vascular prostheses (see, e.g., column 2, lines 17-23). While Merrill's "primary use" may be in protein separations and purifications, this is not relevant to the rejection because all the disclosure of a reference, not just the reference's preferred embodiments, must be considered in determining prima facie obviousness. Merrill teaches that its immobilized polyethylene oxide star molecules have the beneficial property of being non-thrombogenic. Because Herweck et al's implants will also be in blood contact, thrombogenesis will be a concern for Herweck et al, and Merrill provides a solution for avoiding thrombogenesis while still permitting Herweck et al's implants to remain coated with bioactive material. Herweck et al already teach an enhanced rate of target cell growth (see column 6, lines 23-29 and 33-36). This is not an aspect of Applicants' claimed invention which is missing from Herweck et al and which needs to be supplied by the secondary reference. In any event, because Herweck et al's bioactive materials would still be present in the implant of Herweck et al as modified by Merrill, the bioactive materials would still be expected to continue their function of enhancing the rate of target cell growth. Applicants argue that Herweck et al's disclosed desire of encouraging and enhancing cell growth is inconsistent with Merrill's disclosed properties for POE, i.e. that a non-thrombogenic material

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would tend to repel cells. However, Applicants' citation to column 1, lines 6-9, does not support the argument that non-thrombogenic materials tend to repel cells. This section of Merrill mentions only the proteins of the intrinsic clotting system and of the platelet membrane, and does not mention cells. There is no reason to believe that the polyethylene oxide of Merrill would prevent the bioactive materials of Herweck et al from interacting with and stimulating cells which comprise receptors for the bioactive materials.

The examiner agrees that the rejection of claim 17 over Herweck et al in view of Merrill (U.S. Patent No. 5,171,264) and further in view of Mikos will stand or fall with the rejection of claims 14-16 over Herweck et al in view of Merrill (U.S. Patent No. 5,171,264).

The obviousness-type double patenting rejections set forth in the previous Office action are maintained, and the examiner maintains his position that only one-way obviousness is necessary to support the rejections. Applicants and the examiner agree on the correct test for when two-way obviousness is necessary, this test being set forth at page 9, last full paragraph, of Applicants' response. Applicants and examiner disagree as to whether the first condition of this test has been met. While the proposed amendment after final rejection filed September 4, 1997 was denied entry, entry was denied because of the time during prosecution at which the proposed amendment was submitted, i.e. the proposed amendment was submitted after final rejection and at least raised new issues requiring further consideration. See the Decision on Petition mailed December 15, 1997, last paragraph. Note that the court in *In re Berg*, 46 USPQ2d 1226 (Fed. Cir. 1998) emphasizes that the first condition is a question of written description, i.e. the issue is whether the disclosure of the first application supports the second set of claims (see *Berg* at page 1233, second full paragraph). The fact situation in *In re Braat*, 19 USPQ2d 1289 (Fed. Cir.

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1991) is distinguished because in Braat, the later filed application was a continuation-in-part of the first-filed application, and the first-filed application did not support the claims of the later-filed application (see Berg, paragraph bridging pages 1230 and 1231). In the instant situation, the claims of the later filed applications, which issued as U.S. Patent Nos. 5,906,828 and 6,045,818, are necessarily supported by this first-filed application because the later filed applications are continuations, not continuations-in-part, of this first-filed application. The specifications of all three applications are identical as in Berg and in contrast with Braat (see Berg at page 1231, first full paragraph). Further, to require two-way obviousness in this situation, a policy concern of the court in In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993) would be violated: "By adopting the easy course of filing a continuation or divisional application to gain a narrow claim, a patentee could gain an extension of the term on a species when the broader genus later issued. This practice would extend the exclusionary right past the 17-year limit mandated by Congress." Goodman at page 2016, fourth full paragraph.

Because the first condition for two-way obviousness has not been met, it is not necessary to consider the second condition, i.e. who actually controlled the respective rates of prosecution. Compare Berg at page 1232, first full paragraph.

Only one-way obviousness being required, the obviousness-type double patenting rejections are therefore proper.

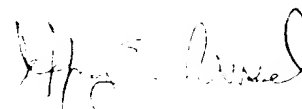
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
October 15, 2002



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